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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,083	10/20/2003	John Allen	LFS-5002	4870

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EXAMINER	
SONNETT, KATHLEEN C	
ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,083	ALLEN ET AL.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, filed 4/23/2007, with respect to the rejection(s) of claim(s) 1-11 in view of Roe et al. (US 2004/0127818) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Sakata et al. and Schraga.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 1-4 and 8-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata et al. (U.S. 2004/0215224) in view of Schraga (U.S. 6,022,366). Sakata discloses a lancing device comprising a lancing mechanism having a lancet carriage (31), a lancet holder (3b) connected to the lancet carriage and a lancet (3a) attached to the lancet holder, a floating probe (7) and a pressure tip (8) for engaging a target site and creating a target site bulge wherein the floating probe is adapted to floatably rest upon the target site bulge as the target site bulge is created by the pressure tip. In the device of Sakata, the floating probe is configured to operatively interact with the lancet holder (3b), instead of the lancet carriage (31), to control a penetration depth of the lancet into the target site bulge. Sakata also fails to disclose that the lancet holder is slidably connected to the lancet carriage (see fig. 15).

4. However, Shraga discloses that it is old and well known to have a lancet holder and carriage slidably connected to each other in order to allow the user to change the penetration

depth if desired (see fig. 3c,3d; "72","74"). In particular, Shraga discloses a lancet holder and lancet carriage that are connected with mating threads that slide past each other in order to change the position of the lancet holder relative to the lancet carriage. Applying this feature to Sakata, it would be advantageous to have the floating probe interact with the lancet carriage instead of the lancet holder so that the depth of penetration can be changed due to the change in position of the holder relative to the carriage without affecting the rest of the lancet. Therefore, it would have been obvious to one skilled in the art to modify the device of Sakata to include a lancet holder which is slidably connected to a lancet carriage and have the floating probe operatively interact with the lancet carriage (31) instead of the holder as made obvious by Shraga in order to gain the advantage of being able to change the depth of penetration.

5. Regarding claim 2, the device includes a housing (20). The lancet carriage and floating probe are slidably connected to the housing.

6. Regarding claim 3, although not expressly disclosed, the floating probe shown in the figures of Sakata does not change shape even when pressed against a tissue bulge and is therefore being considered rigid.

7. Regarding claim 4, Sakata discloses a launcher spring (83) and a decoupling spring (74)

8. Regarding claim 8, the probe stop surface can be considered the surface of (8) where the proximal end of the spring (74) is attached.

9. Regarding claim 9, the modified device of Sakata has a lancet carriage and lancet holder that fit together such that their relative position can be changed to control the depth of penetration of the needle. Using the embodiment shown in fig. 11 Shraga, the bottom wall of the most distal groove (4^{th} groove on fig.) can be considered a lancet holder over-travel stop feature.

10. Regarding claim 10, Sakata as modified by Shraga discloses providing a lancing device that includes a lancet carriage, a lancet holder slidably connected to the lancet carriage, and a lancet attached to the lancet holder, a floating probe, and a pressure tip for engaging a target site and creating a target site bulge, wherein the floating probe is adapted to floatably rest upon the target site bulge as the target site bulge is created by the pressure tip and is configured to operatively interact with the lancet carriage to control a penetration depth of the lancet into the target site bulge, contacting the pressure tip with the target site and urging the pressure tip towards the target site (see fig. 15), thereby creating the target site bulge as the floating probe is floating on a surface of the target site bulge; and lancing the target site bulge with the lancet while the floating probe operatively interacts with the lancet carriage to control a penetration of the lancet.

11. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata et al. in view of Shraga as applied to claim 1 above and further in view of Böcker et al. (U.S. 5,997,561). Modified Sakata discloses the invention substantially as stated above, but fails to disclose that the penetration depth is between 0.25mm and 1.5 mm. However, Böcker et al. discloses that it is old and well known in the art to include a penetration depth of 0.25 mm to 1.5 mm in a lancing device that has a depth of penetration controlling means. Böcker et al. discloses that the penetration depth range can be set between 0.2 and 2.0 mm in order to provide about 100 microliters of body fluid. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Sakata to include a penetration depth of between 0.25 mm and 1.5 mm made obvious by Böcker et al. in order to collect an appropriate amount of fluid for blood sampling.

12. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata in view of Shraga as applied to claim 2 and further in view of Levin et al. (U.S. 4,517,978). Modified

Sakata discloses the invention substantially as stated above but fails to disclose a stop lock assembly.

13. Levin discloses a stop lock assembly (55; 33) that includes a button that is depressed so that arm (33) disengages hole 35 and the lancet is actuated. The user first cocks the device and the stop lock assembly initiates firing of the lancet. Such a configuration causes the lancet to fire and then return inside of the lancet housing so that the needle is kept clean and out of the way after it has punctured the skin (col. 2 ll. 38-58). Therefore, it would have been obvious to one skilled in the art to further modify the device of Sakata to include a stop lock assembly as made obvious by Levin in order to have a lancet that is easily actuated wherein the needle is immediately retracted, keeping it clean, safe and out of the way.

14. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata in view of Shraga as applied to claim 2 and further in view of Levin et al. (U.S. 4,517,978). Modified Sakata discloses the invention substantially as stated above including a floating probe spring (spring 74 now being considered floating probe spring), but fails to disclose an over-travel spring or launching spring that, along with the floating probe spring, are configured to control movement and positioning of the floating probe, lancet carriage, and lancet holder.

15. However, Levin et al. discloses that it is old and well known to include an over-travel spring (45) and launching spring (37) to control movement and position of a lancet carriage and holder (see col. 2 ll. 26-32; fig. 2). A similar series of springs could be added to the device of Sakata to control the movement of lancet holder as it is not disclosed exactly how the position of the lancet holder is maintained when not depressed by the user or how it returns to its original position after actuation. Therefore, it would have been obvious to one of ordinary skill in the art to further modify the device of Sakata to include an over-travel spring and launching spring as

made obvious by Levin et al. in order to provide a control for the positioning and movement of the lancet holder and lancet carriage.

Allowable Subject Matter

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 7/3/2007

GLENN K. DAWSON
PRIMARY EXAMINER